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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,899	02/23/2004	Minoru Fujimori	2004_0290	5937

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Thomas J. Kowalski, Esq.
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151

EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,899	FUJIMORI ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner of record has changed. Please direct all further correspondence to Scott Long whose phone number is 571-272-9048.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 September 2006 has been entered.

Claim Status

Claims 28-46 are pending. Claims 1-27 are cancelled. Claims 28-46 are under current examination.

Sequence Compliance

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

Oath/Declaration

The oath or declaration, having the signatures of all inventors, received on 23 February 2004 is in compliance with 37 CFR 1.63. On 28 March 2006, a document was received that was identified as an Oath. Only one page of the 28 March 2006 document is visible and examiner does not understand the purpose of this filing.

Information Disclosure Statement

The new Information Disclosure Statements (IDS) filed on 28 September 2006 consisting of 1 sheet is in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit as a Continuation of U.S. Application No. 09/816,391 filed 26 March 2001 (abandoned). The instant application also claims benefit from foreign application JAPAN 2000-287688 filed 12 September 2000. The application has been granted the benefit date, 26 March 2001, from U.S. application 09/816,391 because no English translation of foreign application JAPAN 2000-287688 has been submitted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 28 is directed to "a nonpathogenic gene therapy vector of an anaerobic bacterium." The metes and bounds of claim 28 are not clear. Is the gene therapy vector derived from the bacteria? Is the bacteria actually the vector? Is the gene therapy vector the same as the cloning vector? Or is the gene therapy vector something other than the bacteria or the cloning vector? Please clarify. Since all of the remaining claims are dependent from claim 28, they also contain this indefiniteness.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

WRITTEN DESCRIPTION

Claims 28 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the

application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement;* (Federal Register/Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claim 28 and 30-32 is broadly drawn, such that it applies to a genus of *Bifidobacterium Longum* promoters and terminators. However, the working examples provided in the instant application only demonstrate individual species of *Bifidobacterium Longum* promoter and terminator, specifically a DNA located at nucleotides 1-192 of SEQ ID NO:1 and a DNA located at nucleotides 472-600 of SEQ ID NO:1, respectively.

The Revised Interim Guideline for Examination of Patent Applications under 35 USC § 112, p1 "Written Description" Requirement (Federal Register/ Vol 66. No 4, Friday January 5, 2001) states "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (column 3, page 71434), "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH

EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (column 2, page 71436, emphasis added).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "APPLICANT MUST CONVEY WITH REASONABLE CLARITY TO THOSE SKILLED IN THE ART THAT, AS OF THE FILING DATE SOUGHT, HE OR SHE WAS IN POSSESSION OF THE INVENTION. THE INVENTION IS, FOR PURPOSES OF THE 'WRITTEN DESCRIPTION' INQUIRY, *WHATEVER IS NOW CLAIMED.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize the [he or she] invented what is claimed.". (See *Vas-Cath* at page 1116).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Considering the potentially large numbers of polynucleotides encompassed by these claims, the disclosure is not sufficient to show that a skilled artisan would recognize that the applicant was in possession of the claimed invention (genus) commensurate to its scope at the time the application was filed.

Claims 33-34 are dependent from claim 32 and therefore contain all of the issues described above.

SCOPE OF ENABLEMENT – bacteria type

Claims 28-35 and 37-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for delivering to tumor

tissues under anaerobic conditions in an individual with cancer a genetically modified bacterium, comprising administering a genetically modified bacterium to an individual with cancer, wherein the genetically modified bacterium is a *Bifidobacterium longum*, which comprises an expression plasmid vector comprising a DNA sequence coding for an anti-tumor protein, and does not reasonably provide enablement for a method for specifically delivering to tumor tissues under anaerobic conditions in an individual with cancer a genetically modified bacterium, wherein the genetically modified bacterium selected from the group consisting of a genus of *Bifidobacterium*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The field of the invention is using a bacterium from the genus *Bifidobacterium* as a gene delivery vector comprising a gene used in a method of delivering the gene delivery vector to tumor tissues under anaerobic conditions.

The art of record for *Bifidobacterium* as exemplified by Yazawa et al. (Breast Cancer Research and Treatment, Vol. 66, pp. 156-170, 2001) teaches that:

> *Bifidobacterium* is non-pathogenic bacteria found in the intestine of human and some other mammalian animals. These organisms are believed to have health-promoting properties for their host, including increase of the immune response,

> inhibition of carcinogenesis, and protection of the host against viral infections. However, despite increasing attention to this bacterium in many fields, little is known about its genetic property (page 165).

Furthermore, the state of the art for transforming bacterium from the genus *Bifidobacterium* is highly unpredictable as exemplified by Argnani et al. (IDS, Microbiology, Vol. 142, pp. 109-114). Argnani teaches:

> Although electroporation technique has proven to be widely applicable to genetically transform bacterial strains, all Bifidobacterium so far examined have proved refractory to efficient and reproducible transformation (page 109).

Yazawa, whom teaches that, further supports this:

> To be able to exploit the potential of these organisms for cancer gene therapy, detailed knowledge is required about such basic biological phenomena as cellular metabolism, gene expression, protein secretion, and genetics. Yazawa further states that, studies on Bifidobacterium at the molecular level are severely limited in the absence of an efficient transformation. Recently, Matsumura and colleagues developed a system for convenient and reproducible genetic transformation of B. longum (page 169).

The applicants provide several working examples displaying the transformation of *Bifidobacterium longum* with a gene and the deliver of the genetically modified bacterium to tumor-bearing mice (pages 46-61). The delivery displayed that the bacterium specifically targeted the tumors (page 48). In addition, one example displays the production of a genetically modified bacterium comprising a cytosine deaminase

(CD) gene and an example introducing the bacterium, which was specifically expressed only in tumor tissues under anaerobic conditions in tumor-bearing mice (pages 55-61). In view of the instant specification and the art of record for using *Bifidobacterium* as a gene delivery vector, the claimed invention is only enabled for producing and using the *Bifidobacterium longum* comprising a gene for use in specifically delivering to tumor tissues under anaerobic conditions in a mammal because the as-filed specification and the art of record do not provide sufficient guidance for one skilled in the art to reasonably extrapolate from using *Bifidobacterium longum* to using the genus *Bifidobacterium* without an undue amount of experimentation. The art of record display that studies on Bifidobacterium at the molecular level are severely limited in the absence of an efficient transformation. Therefore, the state of the art is considered unpredictable and the as-filed specification does not provide sufficient guidance for one skilled in the art to make and/or use a representative number of bacterium from the genus *Bifidobacterium* as gene delivery vectors.

As a result, it is not apparent how one skilled in the art determines, without undue experimentation, which of the claimed bacterium from the genus *Bifidobacterium* other than the *Bifidobacterium longum* can be genetically modified and used as a gene delivery vector, how is it apparent as to how one skilled in the art, without any undue experimentation, practices any nucleic acid delivery method as contemplated by the claims, particularly given the unpredictability of nucleic acid therapy as a whole and/or the doubts expressed in the art of record.

The court in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 states:

It is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. In re Vaeck, 947 F.2d 48, 496 & n.23. 30 USPQ2d 1438, 1445 &n23 (Fed. Cir. 1991)(citation omitted). Here, however, the teachings set forth in the specification provide no more than a "plan" or "invitation" for those of skill in the art to experiment...; they do not provide sufficient guidance or specificity as to how to execute that plan. See Fiers v. Revel. 984 F.2d.1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); In re Wright, 999 F.2d...[1557], 1562, 27 USPQ2d...[1510], 1514. [Footnote omitted].

On this record, it is apparent that the specification provides no more than a plan or invitation in view of the art of record exemplifying the unpredictability of making and using the claimed species of *Bifidobacterium* (See Argnani), for those skilled in the art to further experiment with different species of claimed genus of *Bifidobacterium* so as to provide a therapeutic method of cancer gene therapy as intended by the as-filed specification at the time the invention was made.

See also Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997)

> ("Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable the public to understand and carry out the invention.")

In view of the art of record and the lack of guidance provided by the specification; the specification does not provide reasonable detail for what protocols are required for successfully transfecting different species *Bifidobacterium*, and it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from the specification to the full breadth of the claimed invention. Therefore, the as-filed specification is not enabled for the full scope of the claimed invention.

In conclusion, the as-filed specification and claims coupled with the art of record at the time the invention was made only provide sufficient guidance and/or evidence to reasonably enable a method for specifically delivering to tumor tissues under anaerobic conditions in an individual with cancer a genetically modified bacterium, wherein the genetically modified bacterium is a *Bifidobacterium longum*, which comprises an expression vector comprising a DNA sequence coding for a protein. Given that efficiently transfecting a representative number of *Bifidobacterium* was unpredictable at the time the invention was made, and given the lack of sufficient guidance as to how to reasonably correlate efficiently transfecting *Bifidobacterium longum* to the other species of *Bifidobacterium* cited in the claims, one skilled in the art would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the applicants' disclosure and the unpredictability of transfecting *Bifidobacterium*.

Applicant's arguments filed 2/1/06 regarding a similar rejection as applied to cancelled claims 4, 6, 7, 10, 11, 14, 16, 21, 24, and 25 are moot because of the cancellation of claims. However, only claim 36 has narrowed the scope of the claims to the gene delivery vector, *Bifidobacterium longum*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yazawa et al. (Proceedings of the American Association for Cancer Research Annual Meeting, Vol. 40, pp. 88, 1999) in view of Brown et al. (US applic. 2003/0103952). Yazawa teaches using *Bifidobacterium longum* as a gene delivery vector for treating cancer in a buffer or solution, which is considered to be a pharmaceutical preparation. However, Yazawa does not specifically teach introducing a DNA coding for a protein

having an activity of converting a precursor of an anti-tumor substance into the anti-tumor substance into a tumor using *Bifidobacterium longum*.

However, at the time the invention was made, introducing a DNA coding for a protein having an activity of converting a precursor of an anti-tumor substance into the anti-tumor substance into a tumor using a genetically modified bacterium was well known to one of ordinary skill in the art as exemplified by Brown (columns 1-26). Brown teaches using a genetically modified bacterium to deliver an enzyme to the hypoxic/necrotic environment of a tumor and systemically administering a pro-drug, which is converted at the site of the tumor to the toxic agent by the enzyme (columns 25-26). The enzyme/prodrug combination can be selected from following: nitroreductase/CB1954; cytosine deaminase/5-fluorocytosine; beta-glucuronidase/glucuronidated anticancer drugs (columns 5-6).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the teaching of Yazawa taken with Brown, namely to use a genetically modified *Bifidobacterium longum* comprising a nucleic acid sequence encoding a protein having an activity of converting a precursor of an anti-tumor substance into the anti-tumor substance in a method to treat tumor tissues under anaerobic conditions. One of ordinary skill in the art would have been motivated to introduce the DNA encoding a protein having an activity of converting a precursor of an anti-tumor substance into the anti-tumor substance into tumor tissues under anaerobic conditions using the genetically modified bacterium because the bacterium is a nonpathogenic anaerobic bacterium, which can selectively localize to solid tumors in an

individual after systemic application and pro-drug cancer therapy was well known to one of ordinary skill in the art for treating tumor tissue.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the teaching of Yazawa taken with Brown, namely to use any enzyme/prodrug combination in the method to treat tumor tissues under anaerobic conditions. One of ordinary skill in the art would have been motivated, as a matter of designer's choice, to use an enzyme/prodrug combination selected from following: nitroreductase/CB1954; cytosine deaminase/5-fluorocytosine; beta-glucuronidase/glucuronidated anticancer drugs because the enzyme/prodrug combinations were well known to one of ordinary skill in the art for treating hypoxic tumor tissue.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Yazawa taken with Brown, namely to use an expression vector that has a promoter and terminator that function in a Bifidobacterium. One of ordinary skill in the art would have been motivated to use a promoter and terminator that function in the Bifidobacterium because one of ordinary skill in the art understands that a promoter and a terminator are required for the vector to express the protein of interest.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's Argument against 103

Although the rejection of claims 4, 6, 7, 10, 12, 14, 16, 19, 21, 24, 25 under 35 USC 103(a) in view of Yazawa et al. (Proceedings of the American Association for Cancer Research Annual Meeting, Vol. 40, pp.88, 1999) in view of Brown et al. (US-6,416,754B1) is moot due to cancellation of claims, the arguments will be considered to the extent to which they apply to the newly submitted claims 28-46.

The applicant argues that there is insufficient motivation to combine Yazawa et al and Brown. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Part of the applicant's argument asserts that Yazawa et al. does not teach or suggest a gene delivery vector. However, Yazawa et al. does, in fact, teach "Bifidobacterium longum...:as gene delivery vectors" (page 88).

Another part of the applicant's argument reasons that the bacterium of Brown et al., *Clostridium acetobutylicum*, as a member of the genus, *Clostridium*, that also includes pathogenic bacteria, is not suitable as a gene delivery vehicle. However, *Clostridium acetobutylicum* produces no toxins, unlike other members of this genus and poses minimal health risk. In fact, Brown et al. explicitly teaches nonpathogenic clostridial strains (column 4, lines 53-54).

The applicant also argues that the specific promoter, terminator, and transformation methods are different between the instant invention and those of Yazawa and Brown. The methods of transformation used by Brown et al. are common to the art. The ferroxidin (Fd) promoter of the expression plasmid in the invention of Brown et al. was perfectly capable of expressing the nitroreductase gene that transforms a prodrug. The invention of Brown et al. is functionally equivalent to the instant invention.

One of ordinary skill in the art would have been motivated to combine the teachings because B. longum selectively targeted tumors (Yazawa et al., p.88), while Brown et al. demonstrated the use of anaerobic bacteria as delivery vectors for genes which can convert prodrugs. Combining the references would produce an anaerobic bacterial gene delivery vehicle capable of targeting tumor cells and converting a nontoxic prodrug into a toxic drug. Yazawa et al. indicate that targeting genes to tumors is an obstacle to gene therapy. The combined teachings solve this problem.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave Nguyen** can be reached on **571-272-0731**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
Patent Examiner
Art Unit 1633

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER